

REMARKS

1. Status of the Claims

Claims 1-3, 9, 10, 12-72, and 75 are pending. Claims 25-72 are withdrawn.

2. Rejections under 35 U.S.C. § 103, Obviousness

a. Claims 1-3, 9-10, 14-24, and 75

The Examiner rejects claims 1-3, 9-10, 14-24, and 75 under 35 U.S.C. § 103 as unpatentable over Kozak, Janjic, and Vermehren. Applicants respectfully traverse.

The Examiner suggests that example 3 teaches O-aliphatic hydrocarbon in carbon 1 position of the glycerol and that the claim language of instant claim 1 does not exclude the possibility of the moiety linked to the phosphate moiety in example 3 of Kozak. Applicants respectfully disagree.

Claim 1 of the present invention specifically describes that R3 is a member selected from the group consisting of phosphatidic acid, phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl inositol, phosphatidyl glycerol, and phosphatidyl serine. These are all naturally occurring hydrophilic moieties and represent a phosphate moiety linked to another moiety or not linked to any moiety (in the case of phosphatic acid). The moiety linked to the phosphate moiety (Q') in example 3 is excluded. That is, the claims do not encompass protease inhibitors such as 4',5,7-trihydroxyisoflavone, a tyrosine kinase. Thus, even if the skilled artisan were to use polymer containing liposomes for the delivery of the prodrug of Kozak, which Applicants contest, he would not arrive at the instant invention as the resultant prodrug would be a tyrosine kinase.

Applicants also note that Kozak teaches that the compound in example 3 is hydrolyzed by PLD in position 3 to release the protein kinase inhibitor. Therefore, the prodrug of Kozak is not the lipid derivative itself, as in the presently claimed invention, but a compound linked to the lipid. Thus, as the Examiner has failed to establish that the active substance is liberated in the form of a lysolipid derivative which is not a substrate for lysophospholipase as required by claim 1, the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, one of

skill would not find the present invention obvious based on the combined disclosures of Kozak, Janijec and Vermehren.

The Examiner states that “the reason for Kozak’s teachings of not to use liposomes is because the liposomes are taken up by the reticuloendothelial system (RES), (liver, macrophages. However, both references of Janijic and Vermehren teach the purpose of linking PEG to the lipid (lipopolymer) that is increase in circulation time of the liposomes without being taken up by the RES.” (Office Action, page 4). Applicants respectfully disagree because, as discussed in the amendment of September 19, 2008, Kozak clearly teaches that one of skill should not formulate the prodrugs into liposomes. (Kozak, column 6, lines 5-8).

b. Claims 12-13 and 22

The Examiner also rejects claims 12-13 and 22 under 35 U.S.C. § 103 as unpatentable over Kozak, Janjic, and Vermehren, further in view of Saxon or Bally.

As discussed above with the rejection of claims 1-3, 9-10, 14-24, and 75, one of skill, combining Kozak and Janijic or Vermehren would not arrive at the presently claimed invention. Neither Saxon nor Bally remedy the deficiencies of Kozak, at least because they do not provide any reasoning why one of skill in the art would substitute the presently claimed R3 moiety for the tyrosine kinase disclosed in Kozak.

c. Unexpected Results

Applicants reiterate the that the Examiner has failed to establish a *prima facie* case of obviousness. However, Applicants note that the Examiner has failed to address the unexpected results found in the Specification in any substantive manner. “Office personnel should not . . . summarily dismiss [evidence of secondary considerations] as not compelling or insufficient. If the evidence is deemed insufficient to rebut the *prima face* case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify” a conclusion that evidence of secondary considerations is insufficient to overcome a *prima face* case of obviousness. MPEP § 2145.

The Examiner states “the properties of the lyso-ether lipids and liposomes are well known.” However, the Examiner does not provide any evidence suggesting that the results

obtained by the Applicants are within the realm of the expected properties of lyso-ether lipids. The Examiner simply provides a conclusory statement without any supporting reasoning. Applicants submit that this statement is insufficient.

As discussed in the Amendment of September 19, 2008, pages 21 and 22, the presently claimed prodrugs have unexpectedly low haemotoxicity compared to lyso-etherlipids of the prior art. Moreover, the present prodrugs performed better than other lipid delivery systems. Applicants submit that these synergistic characteristics overcome any showing of *prima facie* obviousness. Applicants request that the rejection be withdrawn.

CONCLUSION

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$1,110.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Application No. 10/788,974
Amendment dated May 20, 2009
After Final Office Action of November 20, 2008

Docket No.: 2081-0125P

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: May 20, 2009

Respectfully submitted,

By 

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